K063180

510(k) SUMMARY

1. **Submitted by:**

Hospira, Inc.
D-389, Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045
Attn: Diane Rennpferd

Phone: (224) 212-5452
Fax: (224) 212-5401

DEC 1 1 2006

2. **Date Prepared:** October 18, 2006

3. **Name/Classification of Device:**

Adaptor, holder, syringe
Class I, IQG, 21 CFR 890.5050
Syringe, Piston
Class II, FMF, 21 CFR 880.5860

4. **Trade Name of Proposed Device:** iSecure Syringe Cartridge Holder

5. **Predicate Devices:**

Device Name	510(k) Number
Empty Sterile Carpuject® Cartridge Syringe holder Accessory	K820164

6. **Proposed Device Description:**

The proposed change is to combine the Carpuject® cartridge and holder into one preassembled unit thereby eliminating the need for a separate holder. The operating principle remains the same. The modified syringe holder accessory can still be used with both empty and prefilled (not the subject of this 510(k) application) Carpuject® Syringe Cartridges. The proposed name for this modification is the iSecure Syringe Cartridge Holder.

7. **Statement of Intended Use:**

The iSecure Syringe Cartridge Holder is intended for use in the withdrawal and administration of sterile materials under aseptic conditions in accordance with the best judgment of the physician.

8. **Summary of Technological Characteristics of New Device Compared to Predicate Devices**

The iSecure Syringe Cartridge Holder as described in this submission is substantially equivalent to the predicate Empty Sterile Carpuject Syringe Holder Accessory with respect to the following characteristics:

- Both devices are intended to be used with either empty or prefilled (not the subject of this submission) Carpuject cartridges
- The technology and operating principles are the same for both devices

- The plunger rod for both devices is attached to the end of the syringe cartridge to actuate an injection.

The claim for substantial equivalence is supported by the information provided in the 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Diane Rennpferd
Senior Associate, Global Regulatory Affairs Devices
Hospira, Incorporated
275 North Field Drive
Dept. 389, Bldg. H2
Lake forest, Illinois 60045

DEC 1 1 2006

Re: K063180
Trade/Device Name: iSecure Syringe Cartridge Holder
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, IQG
Dated: November 20, 2006
Received: November 21, 2006

Dear Ms. Rennpferd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

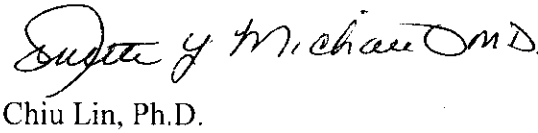
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name: **iSecure Syringe Cartridge Holder**

Indications for Use:

The iSecure Syringe Cartridge Holder is intended for use in the withdrawal and administration of sterile materials under aseptic conditions in accordance with the best judgment of the physician.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW

...Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number: K063180